preventing axial displacement of the prosthesis upon retraction of the tubular member with respect to the bumper member;

wherein the leaflets partially overlap with one another in the closed position.

REMARKS

In the Office Action, the Examiner stated a Restriction Requirement and withdrew claims 21-36 from consideration; objected to the specification; objected to certain terms used in claim 1 and rejected claim 1 under 35 U.S.C. 112; rejected claims 1-4, 6, and 8 under 35 U.S.C. 102(b); and rejected claims 1 and 3-20 under 35 U.S.C. 103(a). In response, Applicants have affirmed the withdrawal of claims 21-36 without prejudice, cancelled claims 2-8 without prejudice, amended the specification and claims 1, 9, 10, and 11, and added new claims 37 through 41. Applicants submit that the subject application is in condition for allowance.

Election / Restrictions

Applicants hereby affirm the provisional election without traverse (previously made by telephone) to prosecute the invention of Group I, claims 1-20.

Specification

Applicants have amended the specification, at page 22, line 9, to refer to United States Patent No. 5,443,500, rather than 5,443,400. This is correction of a clerical error and complies with the Examiner's objection. No new matter is added.

Claim Objections / Claim Rejections Under 35 U.S.C. 112

Applicants have amended claim 1 to comply with the Examiner's objections and rejection under section 112. Although no objection or rejection of claim 11 was stated in the Office Action, Applicants have similarly amended claim 11 to comply with the objections and rejections made to claim 1. Applicants submit that these claims meet the requirements of 35 U.S.C. 112.

Claim Rejections Under 35 U.S.C. 102(b)

The Examiner rejected claims 1-4, 6, and 8 under 35 U.S.C. 102(b) as being anticipated by Wiktor (USP 4,681,110). Without acceding to the Examiner's rejection, and in order to expedite prosecution of the remaining claims, claims 2-4, 6, and 8 have been cancelled and claim 1 has been amended to include the limitations contained in cancelled claim 7, which are not taught or suggested by the Wiktor patent. Accordingly, Applicants submit that the claims, as amended, contain patentable subject matter.

Claim Rejections Under 35 U.S.C. 103(a)

The Examiner rejected claims 1 and 3-20 under 35 U.S.C. 103(a) as being unpatentable over Bramfitt et al. (USP 5,935,135) in view of Martinez et al. (USP 5,453,090). Because neither of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the claims as presently amended, reconsideration and withdrawal of the rejections is respectfully requested.

The Bramfitt patent discloses a balloon delivery system for deploying stents that includes an introducing catheter 10, a stent 30, an inner conduit 24 for introduction of a guidewire, and an outer conduit 26 for introduction of balloon inflation medium. (Col. 3, lines 52-65). The Bramfitt patent fails to teach or suggest several of the features of the present claims, including:

- "a plurality of flexible leaflets integrally molded" to the distal end of the tubular member, as recited in claims 1, 9, 10, 12, 41, and the claims depending therefrom;
- the leaflets "connected to one another by weakened regions", as recited in claims 1 and 37, and the claims depending therefrom;

The Martinez patent, on the other hand, discloses a stent delivery method that includes a sheath 18 with a distal end portion 32 having weakened areas 41-45 or slits 41A-45A. (Col. 4, lines 18-32). However, the Examiner has identified no teaching or suggestion as to why a person of ordinary skill in the art would have been motivated to combine the recited features disclosed in the Bramfitt and Martinez patents. Thus, no prima facie case of obviousness has been made, and the claims must be allowed.

Furthermore, neither of the Bramfitt and Martinez patents teaches or suggests the following features of the present claims:

- the leaflets including a portion having a thickness that is substantially thinner than a wall thickness of the distal portion of the tubular member, as recited in claims 9 and 39;
- the leaflets partially overlapping with one another in the closed position, as recited in claims 40 and 41; and
- the bumper member comprising a helical coil, as recited in claims 10 and 11, and the claims depending therefrom.

Because none of these features is taught or suggested in the cited patents, the Examiner has failed to establish a prima facie case of obviousness for the recited claims. For this additional reason, these claims must be allowed.

The Examiner states that, in regard to former claim 7 (the substance of which has been incorporated into amended claim 1), "it would have been obvious matter of design choice to modify the delivery sheath of Bramfitt et al. in view of Martinez et al. ... to further have weakened regions between the leaflets and the regions being tearable upon retraction of the sheath, since applicant has not disclosed that having the weakened regions between the leaflets solves any stated problem or is for any particular purpose." This basis for rejection is in error for at least the following reasons. First, there is no teaching of the claimed feature in either of the Bramfitt or Martinez patents, as noted above. Second, as also noted above, the Examiner has shown no teaching or suggestion that

would have motivated a person of ordinary skill in the art to combine the teachings of Bramfitt and Martinez in the manner suggested. The Examiner's rejection thus constitutes pure (and improper) hindsight, using Applicants' claims as a guide. Third, it is not required for Applicants to have provided a particular purpose for a feature recited in the claims, nor for Applicants to have identified a particular problem solved by a recited feature. Instead, the burden is on the Examiner to state a prima facie case of obviousness by identifying all of the claimed features in the prior art and by showing that a person of ordinary skill would have been motivated to combine the cited references. Failure to do so, as here, necessarily means that the claims contain patentable subject matter. For at least these reasons, this basis for rejecting claim 1 (i.e., former claim 7) must be withdrawn.

The Examiner further states, in regard to claims 10 and 11-20, that "it would have been obvious matter of design choice to modify the apparatus of Bramfitt et al. in view of Martinez et al. to have a bumper member comprising a helical coil, since applicant has not disclosed that having the bumper member comprising a helical coil solves any stated problem or is for any particular purpose." This basis for rejecting these claims suffers the same fate as the previous one. First, the helical coil bumper member is not taught or suggested by either of the Bramfitt or Martinez patents. Second, even if it were, there is no teaching or suggestion to make the combination. Third, Applicants are not obliged to identify the problems solved by or purpose for any claimed features. Finally, even if Applicants had such an obligation, they have clearly stated in the specification that the helical coil structure may make the bumper member 30 "substantially resistant to buckling or kinking, while facilitating bending of the bumper member 30 transverse to the longitudinal axis 28." (Spec. pg. 18,

line 20 through page 19, line 2). Once again, for at least these reasons, this basis (the only stated basis) for rejecting claims 10 and 11-20 must be withdrawn.

CONCLUSION

In view of the foregoing, it is submitted that the claims presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

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Dated: November 18, 2002

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VERSION WITH MARKINGS SHOWING AMENDMENTS:

IN THE SPECIFICATION:

Page 22, lines 1-19:

In a preferred embodiment, a stent 50 or other tubular prosthesis or graft may be disposed within the lumen 16 of the sheath 12 proximate the distal portion 18. The stent 50 preferably is expandable between a contracted condition that facilitates its loading into the lumen 16 of the sheath 12, and an enlarged condition for engaging a wall of a blood vessel or other body lumen (not shown). In a preferred embodiment, the stent 50 is a coiled-sheet stent, such as that disclosed in U.S. Patent No. [5,443,400] 5,443,500 issued to Sigwart, and/or in co-pending applications Serial Nos. 09/347,845, filed July 2, 1999, and 09/406,984, filed September 28, 1999, the disclosures of which are incorporated herein by reference. The stent 50 may be self-expanding, i.e., may be biased to assume the enlarged condition, but may be compressed and constrained in the contracted condition, for example, by the lumen 16 of the sheath 12. Alternatively, the stent 50 may be plastically deformable, i.e.,

may be substantially relaxed in the contracted condition, but may be forcibly expanded to the enlarged condition, for example, using a balloon catheter, as is known in the art.

IN THE CLAIMS:

1. An apparatus for delivering a prosthesis into a blood vessel of a patient, comprising:

an elongate tubular member having a proximal end, a distal end, and a lumen extending between the proximal and distal ends, the distal end having a size for endoluminal insertion into a blood vessel and terminating in a substantially atraumatic distal portion comprising a plurality of flexible leaflets integrally molded thereto, the leaflets being deflectable from a closed position wherein the leaflets engage one another to an open position wherein the leaflets define an opening communicating with the lumen;

a tubular prosthesis disposed within the lumen proximate the distal portion; and

an elongate bumper member having a proximal end and a distal end, the bumper member being slidably disposed within the lumen of the [sheath] tubular member, the distal end of the bumper member having a blunt edge disposed adjacent [a] the proximal end of the prosthesis for preventing axial displacement of the prosthesis upon retraction of the tubular member with respect to the bumper member;

wherein adjacent leaflets are connected to one another by weakened regions, the weakened regions being tearable upon retraction of the tubular member with respect to the prosthesis to allow the leaflets to be deflected towards the open position.

9. [The apparatus of claim 1,] An apparatus for delivering a prosthesis into a blood vessel of a patient, comprising:

an elongate tubular member having a proximal end, a distal end, and a lumen extending between the proximal and distal ends, the distal end having a size for endoluminal insertion into a blood vessel and terminating in a substantially atraumatic distal portion comprising a plurality of flexible leaflets integrally molded thereto, the leaflets being deflectable from a closed position wherein the leaflets engage one another to an open position wherein the leaflets define an opening communicating with the lumen;

a tubular prosthesis disposed within the lumen proximate the distal portion; and

an elongate bumper member having a proximal end and a distal end, the bumper member being slidably disposed within the lumen of the elongate tubular member, the distal end of the bumper member having a blunt edge disposed adjacent the proximal end of the prosthesis for preventing axial displacement of the prosthesis upon retraction of the tubular member with respect to the bumper member;

wherein the leaflets include a portion having a thickness that is substantially thinner than a wall thickness of the distal portion of the [sheath] tubular member from which the leaflets extend.

10. [The apparatus of claim 1,] An apparatus for delivering a prosthesis into a blood vessel of a patient, comprising:

an elongate tubular member having a proximal end, a distal end, and a lumen extending between the proximal and distal ends, the distal end having a size for endoluminal insertion into a blood vessel and terminating in a substantially atraumatic distal portion comprising a plurality of flexible leaflets integrally molded thereto, the leaflets being deflectable from a closed position wherein the leaflets engage one another to an open position wherein the leaflets define an opening communicating with the lumen;

a tubular prosthesis disposed within the lumen proximate the distal portion; and

an elongate bumper member having a proximal end and a distal end, the bumper member being slidably disposed within the lumen of the elongate tubular member, the distal end of the bumper member having a blunt edge disposed adjacent the proximal end of the prosthesis for preventing axial displacement of the prosthesis upon retraction of the tubular member with respect to the bumper member;

wherein the bumper member comprises a helical coil.

11. (Amended) An apparatus for delivering a prosthesis into a blood vessel of a patient, comprising:

an elongate tubular member having a proximal end, a distal end, and a lumen extending between the proximal and distal ends, the distal end having a size for endoluminal insertion into a blood vessel;

a tubular prosthesis disposed within the lumen proximate the distal end; and

an elongate bumper member comprising a helical coil having a proximal end and a distal end, the bumper member being slidably disposed within the lumen of the [sheath] tubular member, the distal end of the bumper member having a blunt distal edge disposed adjacent [a] the proximal end of the prosthesis for preventing axial displacement of the prosthesis upon retraction of the tubular member with respect to the bumper member.